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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,292	12/01/2003	Juan Armendariz Borunda	5585-036-999	4513

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EXAMINER	
CHEN, SHIN LIN	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/724,292	ARMENDARIZ BORUNDA ET AL.	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 22-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 22-32 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants' amendment filed 2-7-06 has been entered. Claims 22 and 25 have been amended. Claims 28-32 have been added. Claims 22-32 are pending and under consideration.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Mexico on 9-17-99. It is noted, however, that applicant has not filed a certified copy of the Mexico 998515 application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 22 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention and is repeated for the reasons set forth in the preceding Official action mailed 11-7-05. Applicant's arguments filed 2-7-06 have been fully considered but they are not persuasive.

Applicants cite specification [0071] and argue that the specification has provided guidance to one of ordinary skill an exemplary non-limiting unitary dose (amendment, p. 6-7). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 11-7-05. The specification only gives an example of unitary dose but fails to define the phrase "unitary doses of viral particles". It is still unclear as to the

metes and bounds of what would be considered "unitary doses". It is still unclear how many viral particles is considered "unitary dose".

3. Claims 22, 23 and 28-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants' amendment filed 2-7-06 necessitates this new ground of rejection.

The phrase "the therapeutic proteins for the treatment of fibrotic disorders the latent and/or active protein MMP-8, MMP-1, MMP-2, MMP-9 and MMP-3; uPA wild type and/or modified; the truncated receptor for TGF-beta type II; betaglycan; HGF and Smad 7" in claim 22 is vague and renders the claim indefinite. It is unclear which therapeutic protein(s) is intended, MMP-8, MMP-1, MMP-2, MMP-9, MMP-3, any combination of those protein, or all of those proteins, any combination f uPA, TGF, betaglycan, HGF and Smad 7, or all of these protein. Claims 23 and 28-32 depend from claim 22 but fails to clarify the indefiniteness.

The terms "MMP', "uPA", "TGF", "HGF", and Amad 7" in claim 22 is vague and renders the claim indefinite. These terms are abbreviations and they can stand for various different meanings. Spelling out the terms would be remedial.

The term "and/or" in lines 7 and 8 of claim 22 is vague and renders the claim indefinite. It is unclear what is intended. Changing the term "and/or" to "... or ... or both" would be remedial.

4. Claim 28 recites the limitation "the administration route is intravenous" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. There is no

"administration route" in claim 22. Applicants' amendment filed 2-7-06 necessitates this new ground of rejection.

Claim Objections

5. Claims 28-32 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The intended use and the intended organ of the pharmaceutical composition in the newly added claims 28-32 fail to further limit the pharmaceutical composition of claim 22. The pharmaceutical composition of claim 22 is the same as the pharmaceutical composition of claims 28-32.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 22-27 remain rejected and the newly added claims 28-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention and is repeated for the reasons set forth in the preceding Official action mailed 11-7-05. Applicant's arguments filed 2-7-06 have been fully considered but they are not persuasive.

Applicants amended claim 22 to recite the therapeutic proteins for the treatment of fibrotic disorders and argue that said amendment overcome the rejection (amendment, p. 7). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 11-7-05. Claims 22, 23 and 28-32 encompass treating various fibrotic diseases or disorders in a patient by delivering a recombinant adenoviral vector expressing the recited therapeutic protein under the control of a promoter via various administration routes in vivo. Claims 24-27 still encompass treating various fibrotic diseases or disorders in a patient by delivering a recombinant adenoviral vector expressing any therapeutic protein under the control of a promoter via various administration routes in vivo. The specification fails to provide adequate guidance and evidence for delivering a recombinant adenoviral vector expressing any therapeutic protein under the control of a promoter via various administration routes in vivo such that therapeutic effects can be obtained so as to treat any fibrotic disease or disorder in a patient. As discussed in the preceding Official action mailed 11-7-05, the state of the art of gene therapy was not well developed and was highly unpredictable at the time of filing. Different therapeutic proteins have different amino acid sequences and their biological functions would differ. The biological function of a protein was unpredictable from mere amino acid sequence at the time of the invention. Thus, it would have required undue experimentation for one skilled in the art at the time of the invention to practice over the full scope of the invention claimed. Therefore, claims 22-27 remain rejected and the newly added claims 28-32 are rejected under 35 U.S.C. 112 first paragraph.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 22 and 23 remain rejected and the newly added claims 28-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Hattori et al., January 1999 (Human Gene Therapy, Vol. 10, No. 2, pp. 215-222) and is repeated for the reasons set forth in the preceding Official action mailed 11-7-05. Applicant's arguments filed 2-7-06 have been fully considered but they are not persuasive.

The intended use and the intended organ of the pharmaceutical composition in the newly added claims 28-32 fail to further limit the pharmaceutical composition of claim 22. The pharmaceutical composition of claim 22 is the same as the pharmaceutical composition of claims 28-32.

Applicants argue that the instant application claims the priority of foreign application Mexico 998515, filed September 17, 1999, therefore, the cited reference is not available as prior art under 35 U.S.C. 102(b) (amendment, p. 7). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 11-7-05. Applicants fail to file certified copy of the claimed foreign publication Mexico 998515 and no English translation for the foreign publication has been provided. The effective filing date of the instant invention is the filing date of PCT/MX00/00035, filed 9-14-00, which is more than one year later than the publication date of the cited reference. Thus, the claims remain rejected under 35 U.S.C. 102(b). It is noted that even

an English translation for the foreign publication Mexico 998515 is provided, the claims also could be rejected under 35 U.S.C. 102(a).

10. Claim 22 remains rejected and the newly added claims 28-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Jaffe et al., April-May 1999 (Experimental Lung Research, Vol. 25, No. 3, pp. 199-215) and is repeated for the reasons set forth in the preceding Official action mailed 11-7-05. Applicant's arguments filed 2-7-06 have been fully considered but they are not persuasive.

The intended use and the intended organ of the pharmaceutical composition in the newly added claims 28-32 fail to further limit the pharmaceutical composition of claim 22. The pharmaceutical composition of claim 22 is the same as the pharmaceutical composition of claims 28-32.

Applicants argue that the instant application claims the priority of foreign application Mexico 998515, filed September 17, 1999, therefore, the cited reference is not available as prior art under 35 U.S.C. 102(b) (amendment, p. 7). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 11-7-05. Applicants fail to file certified copy of the claimed foreign publication Mexico 998515 and no English translation for the foreign publication has been provided. The effective filing date of the instant invention is the filing date of PCT/MX00/00035, filed 9-14-00, which is more than one year later than the publication date of the cited reference. Thus, the claim remains rejected under 35 U.S.C. 102(b). It is noted that even an English translation for the foreign publication Mexico 998515 is provided, the claim also could be rejected under 35 U.S.C. 102(a).

Conclusion

No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shin-Lin Chen, Ph.D.

SHIN-LIN CHEN
PRIMARY EXAMINER